



## Computerised Systems Validation

Enterprise Resource Planning Systems (ERP)  
Electronic Documentation (EDMS)  
Quality Process Management (CAPA)  
Electronic Contents management (ECM)  
Manufacturing Execution Systems (MES)  
Electronic Batch Record (EBR)  
Electronic Records; Electronic Signatures  
(21 CFR part 11)  
Control and monitoring systems:  
SCADA, DCS, PLC's  
LIMS  
Clinical Data Management and  
Statistical Analysis  
Pharmacovigilance  
Laboratory Data Acquisition (LDAS)  
IT infrastructures Quality Management  
Systems for software development

From data acquisition systems linked to laboratory instruments, to the most complex ERP or Knowledge Management systems, the validation of computerised systems is in today's overall GxP compliance environment a capital issue and one of the favourite subjects covered in inspections by the regulatory authorities.

The technology currently available and the role that IT systems play in the business and quality processes are giving rise to many strategic corporate projects in Pharmaceutical R&D and Manufacturing.

These projects should follow an appropriate System Life Cycle from their conception (GAMP) to ensure the adequate return of investment and the required compliance to the applicable GxP principles, including those related to 21 CFR part 11, EU GMP Annex 11,...

The experience of TDV as an absolute leading company in this field, encompasses many corporate projects developed under a global perspective for international pharmaceutical companies, as well as with suppliers and leading consultancy companies, specialised in systems implementation.

For further information about Computerised  
Systems Validation please contact:  
**Ma Àngels San - [masan@tdvct.com](mailto:masan@tdvct.com)**  
**Sergi Arcas - [sarcas@tdvct.com](mailto:sarcas@tdvct.com)**